January 4, 2019

Verathon Medical (Canada) ULC
% Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street, NW
Buffalo, MN 55313

Re: K183256
Trade/Device Name: GlideScope BFlex™ Single-Use Bronchoscope System
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (flexible or rigid) and accessories
Regulatory Class: Class II
Product Code: EOQ
Dated: December 14, 2018
Received: December 21, 2018

Dear Mark Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely yours,

Srinivas Nandkumar -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183256

Device Name
GlideScope® BFlex™ Single-Use Bronchoscope System

Indications for Use *(Describe)*
GlideScope® BFlex™ Single-Use Bronchoscope System are intended to work with the video monitor, in conjunction with non-powered endoscopic accessories and other ancillary equipment for endoscopy within the airways and tracheobronchial tree in adult patients.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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SECTION E: 510(K) SUMMARY

This summary of Safety and Effectiveness is provided as part of this Premarket Notification in compliance with 21 CFR 807, Subpart E, section 807.92.

Submitter:

Verathon Medical (Canada) ULC
2227 Douglas Road
Burnaby, BC V3W 1P2
Canada

Contact Person:

Teresa Davidson
Director, Regulatory Affairs
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Date Summary Prepared:

October 26, 2018

Establishment Registration Number:

Verathon Medical (Canada) ULC
Registration Number: 9615393
Owner/Operator Number: 9095489

Device Trade or Proprietary Name:

GlideScope® BFlex™ Single-Use Bronchoscope System

Device Common or Usual Name:

Flexible Bronchoscope

Device Classification:

Classification Name	Class	Product Code	Classification Regulation
Bronchoscope (Flexible or Rigid) and Accessories	II	EOQ	21 CFR 874.4680

Review Panel:

Ear, Nose, and Throat

Predicate Device:

The features and functions of the proposed GlideScope® BFlex™ Single-Use Bronchoscope System is substantially equivalent to the previously cleared Ambu® aScope™ 3 5.0/2.2 flexible bronchoscope and monitor system. The 510(k) clearance number and respective clearance date for the predicate device is below:

Predicate Device	510(k) Number	Clearance Date
Ambu® aScope™ 3 5.0/2.2* Ambu® aScope™ 3 Slim 3.8/1.2 Ambu® aView™ Monitor	K130845	November 01, 2013

** The specific Ambu® aScope™ 3 5.0/2.2 is the predicate device size for the proposed GlideScope® BFlex™ Single-Use Bronchoscope System. This size scope is labeled as Regular in Ambu labeling.*

Device Description:

The GlideScope® BFlex™ Single-Use Bronchoscope System consists of a single-use flexible bronchoscope (5.0), a reusable monitor, and a reusable cable. The system is intended to provide real time viewing and recording for a wide range of airway procedures. The GlideScope® BFlex™ Single-Use Bronchoscope System is distributed sterile and is for single use only. The BFlex bronchoscope operates with a portable reusable GlideScope video monitor (GVM) for purposes of image display.

Intended Use:

GlideScope® BFlex™ Single-Use Bronchoscope System are intended to work with the video monitor, in conjunction with non-powered endoscopic accessories and other ancillary equipment for endoscopy within the airways and tracheobronchial tree in adult patients.

Technological Characteristics:

The proposed subject GlideScope® BFlex™ Single-Use Bronchoscope System when compared to the predicate bronchoscope system has similar technological characteristics. See the comparison table below for similarities and differences between the subject and predicate devices.

Technological Characteristic	Predicate Device Ambu aScope 3 System (K130845)	GlideScope® BFlex™ Single Use Sytem (This submission)
Flexible Endoscope	Yes	Yes
Outside diameter of flexible shaft and tip	5.0mm	5.5mm
Inside diameter of working channel	2.0mm	2.1mm
Suction Button	Yes	Yes
Single Use Bronchoscope	Yes	Yes
Sterility	Sterile by Ethylene Oxide (EO)	Same
Control button for tip maneuverability	Yes	Yes
Power Source	Rechargeable Lithium-ion battery	Same
Camera	Yes	Yes
LED Light Source	Yes	Yes
Image Display	Displays image on a reusable monitor	Same
Extended Viewing	Yes	Yes

Performance Testing:

Performance testing has been completed to demonstrate that the proposed GlideScope® BFlex™ Single-Use Bronchoscope System meets the safety and performance requirements established in the design specifications. Comprehensive verification and validation testing included the following:

- System Requirements Testing
- Hardware Verification
- Software Verification
- AAMI / ANSI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance)
- IEC 60601-2-18: Edition 3.0 2009-08
  Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment
- ANSI AAMI IEC 60601-1-2:2007/(R)2012

- Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (Edition 3)
- ISO 8600-1 Fourth Edition 2015-10-15
  Endoscopes - Medical endoscopes and endotherapy devices -- Part 1: General requirements
- SO 8600-3 First edition 1997-07-01 (Amendment 1 2003-12-01
  Optics and Optical instruments - Medical endoscopes and endoscopic accessories - Part 3: Determination of field of view and direction of view of endoscopes with optics [Including: Amendment 1 (2003)]
- ISO 8600-4 Second Edition 2014-03-15
  Endoscopes - Medical endoscopes and certain accessories - Part 4: Determination of maximum width of insertion portion
- ANSI AAMI ISO 10993-1:2009/(R)2013
  Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- Aging Performance Testing
- Sterile Packaging Integrity Testing
- Cleaning Testing
- Design Validation

Results: All testing resulted in acceptance criteria passed.

Summary of Clinical Tests:

The GlideScope® BFlex™ Single-Use Bronchoscope System, subject of this submission, did not require clinical studies to support the determination of substantial equivalence.

Conclusion:

The information in this 510(k) Premarket Notification demonstrates that the proposed GlideScope® BFlex™ Single-Use Bronchoscope System is substantially equivalent to the previously cleared predicate Ambu® aScope™ 3 5.0/2.2, Ambu® aScope™ 3 Slim 3.8/1.2, and Ambu® aView™ Monitor bronchoscope system with respect to safety, effectiveness and performance.